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UNSEALED 3/20/14



**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF TEXAS**
**McALLEN DIVISION**

| | | | |
|---|---|---|---|
| **UNITED STATES OF AMERICA** | § | | |
| | § | | |
| **v.** | § | **Criminal No.** | M-14-405 |
| | § | | |
| **ELVA NAVARRO** | § | | |

**SEALED INDICTMENT**

**THE GRAND JURY CHARGES:**

Introduction

At all times relevant to this Indictment:

1. The United States Food and Drug Administration is the agency of the United States charged with the responsibility of protecting the health and safety of the American public by ensuring the safety and effectiveness of drugs and devices distributed in the United States, among other things.

2. Title 21, United States Code, Section 321(h)(3) defines "device" as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or similar or related article, including any component, part, or accessory, which is intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent on being metabolized for achievement of its primary purposes.

3. A "prescription device" is a device that, because of any potential for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe except under the supervision of a practitioner licensed by law to direct the use of such device. *See* 21 C.F.R. § 801.109.

4. Title 21, United States Code, Section 331(c) prohibits the receipt in interstate commerce any food drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery

or proffered delivery thereof for pay or otherwise.

5. Title 21, United States Code, Section 331(k) prohibits the alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling, or the doing of any other act with respect to a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale, whether or not the first sale, after shipment in interstate commerce and results in such article being adulterated or misbranded.

6. Under Title 21, United States Code, Section 351(f)(1)(B), a device is "adulterated" if it is required to, yet does not, have in effect an approved application with the Food and Drug Administration for its intended use or an exemption from the approval requirement before being marketed.

7. Under Title 21, United States Code, Section 352(f)(1), a device is "misbranded" if its labeling lacks adequate directions for use. Under Title 21, Code of Federal Regulations, Section 801.5, "adequate directions for use" means directions under which a layman can use a device safely and for the purposes for which it was intended. By definition, prescription devices cannot have directions that allow a layman to use them safely and for the purposes for which they were intended.

8. Defendant Elva Navarro is not a licensed medical practitioner.

9. Defendant Elva Navarro owns a facility named Bella Face and Body Spa in McAllen, Texas and that is where she would administer injections of liquid silicone into humans.

10. The liquid silicone used by defendant Elva Navarro is a prescription medical device subject to the regulation of the Food and Drug Administration.

11. The liquid silicone used by defendant Elva Navarro required an FDA-approved application and lacked such approved application.

12. Defendant Elva Navarro falsely represented to customers and victims to whom she administered the liquid silicone injections that these were safe when in fact they were not.

Method and Means of the Scheme and Artifice

13. As part of the scheme and artifice to defraud, the defendant Elva Navarro would procure prospective clients for injection of the silicone by making false statements as to the qualifications of the defendant to install such devices, the identity and safety of the devices to be used and the effectiveness of the procedures.

14. As part of the scheme and artifice, the defendant Elva Navarro would obtain these devices from outside the state of Texas or the materials used to make these devices came from outside the state of Texas.

15. As part of the scheme and artifice, the defendant Elva Navarro would receive money for these procedures.

**COUNT ONE**

16. The allegations in paragraphs 1 through 15 are re-alleged and incorporated as if fully set forth in this paragraph.

17. On or about October 5, 2013, in the Southern District of Texas and within the jurisdiction of the Court, defendant,

**ELVA NAVARRO**

with the intent to defraud and mislead Zenyasent Cisneros Reyes, received in interstate commerce a device that was adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B), namely a liquid silicone injection, and the defendant delivered and proffered delivery of the adulterated device to Zenyasent Cisneros Reyes for pay or otherwise.

In violation of Title 21, United States Code, Sections 331(c), 333(a)(2) and Title 18, United States Code, Section 2.

**COUNT TWO**

18. The allegations in paragraphs 1 through 15 are re-alleged and incorporated as if fully set forth in this paragraph.

19. On or about October 5, 2013, in the Southern District of Texas and within the jurisdiction of the Court, defendant,

**ELVA NAVARRO**

with the intent to defraud and mislead Zenyasent Cisneros Reyes, caused a device to be misbranded within the meaning of 21 U.S.C. § 352(f)(1), namely a liquid silicone injection, while it was held for sale after shipment in interstate commerce, in that the liquid silicone injected into the buttocks of Zenyasent Cisneros Reyes was a prescription device whose labeling lacked adequate directions for use under 21 C.F.R. § 801.5.

In violation of Title 21, United States Code, Sections 331(k), 333(a)(2) and Title 18, United States Code, Section 2.

A TRUE BILL

FOREPERSON

KENNETH MAGIDSON
UNITED STATES ATTORNEY

Kimberly Ann Leo

ASSISTANT UNITED STATES ATTORNEY